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EVELYN H MCCONATHY ESQUIRE
DILWORTH PAXSON LLP
2200 MELLON BANK CENTER
1735 MARKET STREET
PHILADELPHIA, PA 19103

EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 07/30/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/460,605

Applicant(s)
Disher

Examiner
Gollamudi Kishore

Art Unit
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 20, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 13-20, 23, and 25-28 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 13-20, 23, and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

The request for the extension of time, filing under 1.114 and the amendment dated 5-20-02 are acknowledged.

Claims included in the prosecution are 1-8, 10, 13-20, 23 and 25-28.

Claim Rejections - 35 U.S.C. § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 14-16, 21, 23, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 15, 16, 21, 23, 27 and 28 provide for the use of the polymersomes, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 15-16, 21, 23, 27 and 28 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process

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claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Furthermore, claims 15 and 16 are confusing. According to claim 15, the material is removed from the surrounding environment; however, claim 16 recites the delivery of the material to the environment (patient). Similar is the case with claims 26-28. These claims need to be restructured.

The distinction between a 'drug', 'a therapeutic composition' and a 'medicament' in claim 28 is unclear. Similar is the case with a 'nutrient', 'sugar', 'vitamin' and a 'mineral' (also in claim 14). In claim 14, it is unclear what 'waste product' is intended to convey.

Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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5. **Claims 1-4, 10, 13-15 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ding (J. Phys. Chem., 1998) or Cornelissen (1998) or Fendler (Science, 1984) all are of record.**

The above references teach polymeric vesicles having a membrane; the polymers are diblock polymers (note abstracts in each). The references meet the requirements of instant claims.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant in general argues that the definitions for the terms have been given in the specification on pages 13 and 14. This argument is not persuasive since as already pointed out before, the claims are given the broadest reasonable interpretation and in instant case the cited references read on instant claims. If applicant's intend is to claim specific composition, then the critical features defining applicant's composition and differentiating from the prior art should have been recited.

Applicants argue that Ding teaches vesicles only through the addition of organic solvents and does not teach vesicle formation in water or aqueous solution. The examiner disagrees and points out to col. 1, page 6111 where Ding discloses preparation in water containing NaCl salt.

Applicant's arguments with regard to Fendler are not found to be persuasive. Applicant argues that Fendler teaches the formation of only structures from small lipid-like amphiphiles with no more than four covalently cross-linkable bonds and that Fendler's

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formulations lack key characteristics of polymers, and only after vesicle-type formation does surfactant polymerization follow according to Fendler. These arguments are not found to be persuasive since instant claims as recited do not distinguish over Fendler. The differences argued are not reflected in the claims.

Applicant argues that under but a single solution condition, Cornelissen reports the formation of bilayer filaments, a left-handed superhelix and collapsed vesicles and thus, in light of the co-existence of multiple structures, Cornelissen teaches not vesicles alone, but multiple structures in co-existence. This argument is not found to be persuasive since instant claim language does not exclude these structures; furthermore, a careful review of instant specification indicates the instant vesicles in dominant co-existence with rod-like and spherical micelles (see the Fig. 1B description on page 9 of the specification).

6. Claims 1-4, 6, 10, 13-18 and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Hentze (Macromolecules, 1999) of record.

Hentze teaches polymeric vesicles having a membrane; the polymers are diblock polymers (note abstract). The reference meets the requirements of instant claims.

Applicants' arguments have been fully considered, but are not found to be persuasive. Applicants argue that they find no description or mention of 'vesicles' in the title, abstract or results. Applicants are incorrect; Hentze clearly teaches lamellar structures (note figures 4 and 5) and col. 1, page 5807, he clearly mentions the term,

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vesicles. Applicant's arguments based on page 14 of instant specification are not persuasive and this point has been addressed above.

7. Claims 1-2, 7-8, 14-18 and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Liu (Macromolecules, 1999) of record.

Liu teaches polymeric vesicles having a membrane, acryloylphospholipids which are cross-linked (note abstract). The reference meets the requirements of instant claims.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant is incorrect in stating that Liu fails to disclose vesicles. Liu on page 5520 clearly teaches vesicles.

Claim Rejections - 35 U.S.C. § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 3-8, 10 and 14-20, 23 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding, Fendler or Hentze cited above.

The references of Ding, Fendler and Hentze are all suggestive of the potential applications of the polymeric vesicles for the drug delivery. The use of the polymeric systems taught by Ding, Fendler or Hentze for drug delivery would have been obvious to one of ordinary skill in the art since these references are suggestive of the drug delivery.

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The criticality of a triblock polymer is not readily apparent to the examiner since from the references it would appear that the amphophilic nature of the polymer is the determinant factor.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again are based on presumed lack of teachings of vesicles in the prior art. These arguments have been addressed above. As to applicant's arguments that none of the references teaches the use of the vesicles for drug delivery, the examiner points out that all of the references cited clearly teach the application of these polymers for drug delivery (note the Introduction section in Henselwood and the conclusion sections in others).

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

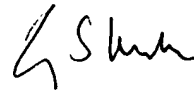
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

July 26, 2002